

REMARKS

Reconsideration of this application is respectfully requested. Claims 11-14, 25-36 and 40-44 have been canceled without prejudice or disclaimer. New claims 45 and 46 have been added and are supported by the originally filed specification. Consideration and entry of this amendment is respectfully requested. Applicants reserve the right to prosecute any withdrawn or otherwise unclaimed subject matter found within this application in a subsequently filed continuation or divisional application.

Information Disclosure Statement

An Information Disclosure Statement and corresponding PTO/SB/08B is submitted with this response.

Restriction Requirement

It is understood that the restriction requirement as to Groups II, III and IV is final. The claims corresponding to the non-elected groups have been cancelled by this amendment.

Objections to the Claims

Claim 4 stands objected to as to the phrase “the oral dosage form of any of claims 1-13”; the Examiner suggested correction to “the oral dosage form of any one of claims 1-13”. Claim 4 has been amended accordingly and withdrawal of this objection is respectfully requested.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 38 stands rejected under 35 U.S.C. § 112, second paragraph as being indefinite because the limitations in sections (a) and (b) were identical. Claim 38 has been amended to correct this typographical error. Withdrawal of this rejection is therefore respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

A. Rejections in view of Palermo (WO 99/32120)

Claims 1-10, 15-24, and 37-39 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of Palermo (WO 99/32120). Applicants respectfully traverse these rejections as indicated below.

The Examiner alleged that although Palermo does not explicitly describe the claimed dissolution profiles, the same “can be determined by one of skill in the art through routine or manipulative experimentation to obtain optimal results as these are variable parameters attainable within the art” and no unexpected or superior results have been demonstrated. The Examiner alleges that Palermo teaches oral dosage forms that are effective for a “twenty-four hour duration”. However, the Examiner has not clearly articulated why the skilled artisan, having Palermo’s allegedly successful disclosure in hand (and not the instant application), would have been drawn to the instantly claimed dissolution profiles. The Examiner is required to clearly communicate each aspect of an obviousness rejection. As stated at MPEP 706.02(j):

“To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.”
Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985)

The mere fact that the prior art may be modified does not make the modification obvious unless the prior art suggests the desirability thereof. In re Lalu, 747 F.2d 703, 223 USPQ 1257 (Fed. Cir. 1984). In the absence of any further explanation as to why these dissolution profiles would have been desired by those of skill in the art at the time of Applicants’ invention, Applicants do not believe the Examiner has established a *prima facie* case of obviousness. Accordingly, it is respectfully requested that this rejection be withdrawn.

B. Rejections in view of Miller (U.S. Pat. No. 6,326,027)

Claims 1, 4-10, 15-24, and 37-39 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of Miller (U.S. Pat. No. 6,326,027). Applicants respectfully traverse these rejections as indicated below.

The Examiner alleged that although Miller does not explicitly teach the claimed dissolution profiles, the same “can be determined by one of skill in the art through routine or manipulative experimentation to obtain optimal results as these are variable parameters attainable within the art” and no unexpected or superior results have been demonstrated. The Examiner alleges that Miller teaches controlled release dosage forms that “provide analgesia effects for the treatment of pain for a twenty-four hour period or greater” with “very low release rates” (e.g., great than 24 or 36 hours). However, the Examiner has not clearly articulated why the skilled artisan, having Miller’s allegedly successful disclosure in hand (and not the instant application), would have been drawn to the instantly claimed dissolution profiles. The Examiner is required to clearly communicate each aspect of an obviousness rejection. As stated at MPEP 706.02(j):

“To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.”
Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985)

The mere fact that the prior art may be modified does not make the modification obvious unless the prior art suggests the desirability thereof. *In re Lalu*, 747 F.2d 703, 223 USPQ 1257 (Fed. Cir. 1984). In the absence of any further explanation as to why these dissolution profiles would have been desired by those of skill in the art at the time of Applicants’ invention, Applicants do not believe the Examiner has established a *prima facie* case of obviousness. Accordingly, it is respectfully requested that this rejection be withdrawn.

C. Rejections in view of Olsson (U.S. Pat. No. 5,952,005)

Claims 1-10, 15-24, and 37-39 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of Olsson (U.S. Pat. No. 5,952,005). Applicants respectfully traverse these rejections as indicated below.

The Examiner alleged that although Olsson does not explicitly teach the claimed dissolution profiles, the same “can be determined by one of skill in the art through routine or manipulative experimentation to obtain optimal results as these are variable parameters attainable within the art” and no unexpected or superior results have been demonstrated. The Examiner alleges that Olsson teaches “controlled release, multiple dosage forms comprising the opioid analgesic, morphine, which provides analgesia effects for the treatment of pain for a twenty-four hour period after administration”. The Examiner also alleges that Olsson’s compositions provide for a mean serum concentration of morphine of “at least 50% of the maximum serum concentration during at least 12 hours” after administration. The Examiner has not clearly articulated why the skilled artisan, having Olsson’s allegedly successful disclosure in hand (and not the instant application), would have been drawn to the instantly claimed dissolution profiles. The Examiner is required to clearly communicate each aspect of an obviousness rejection. As stated at MPEP 706.02(j):

“To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.”
Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985)

The mere fact that the prior art may be modified does not make the modification obvious unless the prior art suggests the desirability thereof. In re Lahu, 747 F.2d 703, 223 USPQ 1257 (Fed. Cir. 1984). In the absence of any further explanation as to why these dissolution profiles would have been desired by those of skill in the art at the time of Applicants’ invention, Applicants do not believe the Examiner has established a *prima facie* case of obviousness. Accordingly, it is respectfully requested that this rejection be withdrawn.

CONCLUSIONS

Applicants believe the claims are in condition for allowance and respectfully request that a Notice of Allowance be issued as soon as possible. The Examiner is encouraged to contact the undersigned with any comments and / or questions.

Respectfully submitted,

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